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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/544,632	04/06/2000	Goro Hori	506.35379CC2	9269
20457	7590	02/20/2004	EXAMINER	
ANTONELLI, TERRY, STOUT & KRAUS, LLP 1300 NORTH SEVENTEENTH STREET SUITE 1800 ARLINGTON, VA 22209-9889			KISHORE. GOLLAMUDI S	
			ART UNIT	PAPER NUMBER
			1615	

DATE MAILED: 02/20/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/544,632

Applicant(s)

HORI ET AL.

Examiner

Gollamudi S Kishore, PhD

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 November 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 17, 18, 28-36, 38 and 42-48 is/are pending in the application.
- 4a) Of the above claim(s) 17 and 28-34 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 18, 35, 36, 38 and 42-48 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>11-7-03</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The amendment dated 11-7-03 is acknowledged.

Claims included in the prosecution are 18, 35-36, 38 and 42-48.

Claim Rejections - 35 U.S.C. ' 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.
2. Claims 18, 35-36, 38 and 42-48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sugano (J. Nutr., 1990) or Sugano (Atherosclerosis, 1988) by themselves or in combination with Imaizumi (Agri. Biol. Chem., 53, (9), 1989 of record.

As pointed out before, the references of Sugano teach the effectiveness of soybean protein-phospholipid complexes in lowering the cholesterol levels (note the abstracts and Tables in both). The amounts of phospholipids in Sugano however, are lower than the amounts in instant invention.

Imaizumi teaches that the administration of phospholipids causes the reduction in the serum cholesterol levels (note the abstract).

It would have been obvious to alter the amounts of the phospholipids in the phospholipid-soy protein complex in Sugano, with the expectation of obtaining the best possible results, since Imaizumi teaches that phospholipids by themselves lower the cholesterol. The criticality of the enzyme-modified phospholipid is not readily apparent to the examiner; as pointed out above, the specification does not provide a definition or experiments conducted with this product.

Applicant's arguments have been fully considered, but are not found to be persuasive. Applicant argues that both references of Sugano focus on the effect of reducing serum and liver cholesterol by an indigested high molecular fraction of soybean protein obtained after microbial protease digestion and that these references do not teach that the effect is due to the complex of protein and phospholipid. These arguments are not found to be persuasive. First of all, as pointed out before, Sugano's compositions contain even phospholipid (see page 116, col. 2 of Atherosclerosis for example) and there is nothing in Sugano to indicate that the phospholipid is not in association with the protein (complex) and instant claims do not define the term, 'complex'. Secondly, even assuming that the phospholipid in Sugano is not in a complex

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form, Sugano observes cholesterol lowering effect due to the protein and small amount of phospholipid and the secondary reference of Imaizumi clearly shows that phospholipids themselves cause a reduction in the cholesterol levels. Therefore, one of ordinary skill in the art would manipulate the levels of phospholipid in Sugano to obtain the best possible results. With regard to applicant's arguments based on enzyme modified phospholipid (page 8 of the response) :- applicant points out to Table 2 of the specification which according to applicant shows lower cholesterol amounts (group 4) compared to group 1. A careful review of the results in Table 2 (page 9 of the specification) shows no differences in cholesterol levels between groups 2-4. It is interesting to note that there are no significant differences between group 2 values wherein the rats were fed 0.8 % phospholipid in bound form and 20 % phospholipid in free form and group 3 values wherein the rats were fed 20 % bound phospholipid and 1% free cholesterol.

Applicant's arguments have been fully considered, but are not found to be persuasive. Applicant's arguments with regard to Sugano and Imaizumi have been addressed above.

3. Claims 18, 35-36, 38 and 42-48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sirtori (Ann. Nutr. Metab. 1985) in combination with Williams (Perspectives in Biology and Medicine, 1984).

Sirtori teaches the effectiveness of lecithinated soy proteins in lowering cholesterol (note the abstract). The amount of lecithin in the complex however, is lower than the amount in instant invention.

Williams teaches the effectiveness of phospholipids in cholesterol removal (note the entire article).

It would have been obvious to alter the amounts of the phospholipids in the lecithinated soy proteins in Sirtori with the expectation of obtaining the best possible results since Williams teaches that phospholipids by themselves lower the cholesterol.

Therefore, it would have been obvious to vary the amounts of lecithin in the compositions of Sugano, 1990 and 1988 since as pointed out above, Williams teaches that phospholipids by themselves lower the cholesterol and Jenkins teaches that the level of dietary lecithin controls the effect of the source and type of protein on the lipid metabolism.

Applicant's arguments have been fully considered, but are not found to be persuasive. Applicant argues that although Sirtori teaches that low-lipid diet with total replacement of animal proteins with textured soy proteins containing 6 percent of lecithin reduces serum total cholesterol, Sirtori is silent about the effect of a protein/phospholipid complex in which the content of bound phospholipid is from 20 % to 50 %. These arguments are not found to be persuasive since Sirtori teaches the very fact that Sirtori uses the expression lecithinated soy proteins indicates that lecithin is associated with the protein and as pointed out above, instant claims do not recite the nature of instant complex. Furthermore, as discussed above, a review of the results in Table 2 of the specification indicates no significant differences between group 2 values wherein the rats were fed 0.8 % phospholipid in bound form and 20 % phospholipid in free form and group 3 values wherein the rats were fed 20 % bound phospholipid and

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1% free cholesterol. With regard to the lower amounts of lecithin in Sirtori, the examiner points out in view of the findings of Williams that phospholipids themselves remove cholesterol, one skilled in the art would vary the phospholipid amounts with the expectation of obtaining the best possible results.

Applicant's arguments based on the declaration have been fully considered, but are not found to be persuasive. Applicant once again argues that figures 1 and 2 show the lowering of cholesterol. The examiner once again points out that these figures show no cholesterol values for soy protein by itself and lecithin by itself (controls) in order to assess the synergistic effect. As also pointed out before, the data presented in Table II of the declaration appears to show an additive effect with regard to both serum cholesterol and the liver cholesterol; as evident from the prior art, soybean protein and lecithin each by itself has the ability to lower cholesterol and therefore, an additive effect is to be expected and it is not an unexpected finding. Secondly, these studies were performed with only soybean protein and not with hydrolysates or wheat protein; claims recite these besides soybean protein. The studies are also not commensurate with the scope of the claims in terms of enzyme modified phospholipids or lecithin.

Upon consideration, the rejections involving the reference of Jenkins have been withdrawn.

1. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within

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TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gollamudi S Kishore, PhD whose telephone number is (571) 272-0598. The examiner can normally be reached on 6:30 AM- 4 PM, alternate Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Gollamudi S Kishore, PhD
Primary Examiner
Art Unit 1615

GSK